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Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment) Interim

Review Draft -For Public Comment

Office of Emergency and Remedial Response U.S. Environmental Protection Agency Washington, D.C. 20460

DISCLAIMER

This document provides guidance to EPA Regions concerning how the Agency intends to exercise its discretion in implementing one aspect of the CERCLA remedy selection process. The guidance is designed to implement national policy on these issues.

Some of the statutory provisions described in this document contain legally binding requirements. However, this document does not substitute for those provisions or regulations, nor is it a regulation itself. Thus, it cannot impose legally-binding requirements on EPA, States, or the regulated community, and may not apply to a particular situation based upon the circumstances. Any decisions regarding a particular remedy selection decision will be made based on the statute and regulations, and EPA decisionmakers retain the discretion to adopt approaches on a case-by-case basis that differ from this guidance where appropriate. EPA may change this guidance in the future.

ABOUT THIS DOCUMENT

WHAT IT IS

This document is Interim Supplemental Guidance (Part E) to the *Risk Assessment Guidance* for Superfund, Volume I: Human Health Evaluation Manual (RAGS). This document incorporates and updates the principles of the EPA interim report, Dermal Exposure Assessment: Principles and Applications (DEA) (U.S. EPA, 1992a), released by the Office of Health and Environmental Assessment (OHEA), in the Office of Research and Development (ORD), in January 1992. RAGS Part E is intended to provide a consistent methodology for assessing the dermal pathway for Superfund human health risk assessments and supersedes any previous dermal risk assessment guidance.

FOR WHOM

This guidance document is for risk assessors, risk assessment reviewers, remedial project managers (RPMs), and risk managers involved in Superfund site investigations and human health risk assessments.

WHAT IS NEW

RAGS Part E updates or expands the following elements in dermal risk assessment methodology:

- **S** updated dermal exposure assessment equations for the water pathway
- **S** updated table for screening contaminants of potential concern (COPCs) from contaminants in water
- **S** specific dermal absorption from soil values for ten chemicals and recommended defaults for screening other organic compounds
- **S** updated soil adherence values based on receptor activities
- **S** updated dermal exposure parameters that are consistent with the *Exposure Factors Handbook* (U.S. EPA, 1997a)
- **S** an expanded Uncertainty Analysis section that discusses and compares the contribution of specific components to the overall uncertainty in a dermal risk assessment.

PEER

This guidance document has been reviewed by internal EPA peer review (May 1997), external

REVIEW

peer review (January 1998), and followup external peer review (January 2000). In addition, specific technical recommendations were provided by a Peer Consultation Workshop organized by the Risk Assessment Forum (December 1998).

DISTRIBU-TION PLAN

This guidance document is being released as an interim document designated as RAGS Part E. This release accompanies a Federal Register Notice requesting public comment and soliciting additional data. Specific information and data tables within this document are available on the

EPA WebPage:

http://www.epa.gov/superfund/programs/risk/ragse/index.htm

ABOUT THIS DOCUMENT(continued)

WHERE TO Senior Process Manager for Risk

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COMMENTS U.S. Environmental Protection Agency

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PREFACE

This guidance is the fifth part (Part E) in the series *Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation Manual* (RAGS/HHEM) (U.S. EPA, 1989). Part A of this guidance describes how to conduct a site-specific baseline risk assessment. Part B provides guidance for calculating risk-based concentrations that may be used, along with applicable or relevant and appropriate requirements (ARARs) and other information, to develop preliminary remediation goals (PRGs) during project scoping. PRGs and final remediation levels can be used throughout the analyses in Part C to assist in evaluating the human health risks of remedial alternatives. Part D complements the guidance provided in Parts A, B and C and presents approaches to standardizing risk assessment planning, reporting and review. Part E is intended to provide a consistent methodology for assessing the dermal pathway for Superfund human health risk assessments. It incorporates and updates principles of the EPA interim report, *Dermal Exposure Assessment: Principles and Applications* (U.S. EPA, 1992a).

Several appendices are included in this guidance to support the summary calculations presented in the main body of the document (Appendix A), to provide physical constants for specific chemicals (Appendix B), and to provide tables for screening chemicals for the pathway (Appendix C). Appendix D provides sample calculations.

ACRONYMS/ABBREVIATIONS

Abbreviation Definition a, b, c Correlation coefficients which have been fitted to the Flynn's data to give Equation 3.8 ABS Dermal absorption from soil ABS _d Fraction of contaminant absorbed dermally (dimensionless) ABS _{GI} Fraction of contaminant absorbed in gastrointestinal tract (dimensionless) AF Adherence factor of soil to skin (mg/cm²-event) ARARS Applicable or Relevant and Appropriate Requirements AT Averaging time (days) Constant specific for the medium through which diffusion is occurring B Dimensionless ratio of the permeability coefficient of a compound through the stratum corneum relative to its permeability coefficient across the viable epidermis (dimensionless)
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corneum relative to its permeability coefficient across the viable epidermis (dimensionless)
CERCLA Comprehensive Environmental Response, Compensation, and Liability Act
BW Body weight (kg)
CF Conversion factor (10 ⁻⁶ kg/mg)
COC Contaminant of Concern
COPC Contaminant of Potential Concern
cPAH Carcinogenic polynuclear aromatic hydrocarbons
C _{soil} Chemical concentration in soil (mg/kg)
C _{tot} Total concentration of chemical in the aqueous solution (mg/l)
C _u Concentration of the non-ionized species (mg/l)
C _w Chemical concentration in water (mg/cm³)
DA _{event} Absorbed dose per event (mg/cm²-event)
DAD Dermal absorbed dose (mg/kg-day)
$D_{\rm e}$ Effective diffusivity of the absorbing chemical in the epidermis (cm ² /hr)
D_{o} Diffusivity of a hypothetical molecule with a molecular volume (MV) = 0 (cm ² /hr)
D_{sc} Effective diffusion coefficient of the chemical through the stratum corneum
DEA Dermal Exposure Assessment: Principles and Applications (U.S. EPA, 1992a)
ED Exposure duration (years)

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EF Exposure frequency (days/year)

ACRONYMS/ABBREVIATIONS (continued)

Acronym/		
Abbreviation	Definition	
EFH	Exposure Factors Handbook (U.S. EPA, 1997a)	
EPA	U. S. Environmental Protection Agency	
EPC	Exposure point concentration	
EPD	Effective Prediction Domain	
EV	Event frequency (events/day)	
FA	Fraction absorbed water (dimensionless)	
FTSA	Fraction of total surface area for the specified body part	
GI	Gastrointestinal	
GSD	Geometric standard deviation	
HHEM	Human Health Evaluation Manual	
IR	Water ingestion rate (liters/day)	
$K_{\rm ew}$	Equilibrium partition coefficient between the epidermis and water for the absorbing chemical	
	(dimensionless)	
K_{ow}	Octanol/water partition coefficient (dimensionless)	
K_p	Dermal permeability coefficient of compound in water (cm/hr)	
K_{p-msd}	Measured dermal permeability coefficient of compound in water (cm/hr)	
$K_{p ext{-pred}}$	Predicted dermal permeability coefficient of compound in water (cm/hr)	
$K_{p,ve}$	Steady-state permeability coefficient through the viable epidermis (ve) (cm/hr)	
$K_{\rm sc/w}$	Equilibrium partition coefficient between the stratum corneum and water (chemical specific	
	dimensionless)	
L_{e}	Effective thickness of the epidermis (cm)	
l_{sc}	Apparent thickness of stratum corneum (cm)	
MV	Molar volume (cm³/mole)	
MW	Molecular weight (g/mole)	
IRIS	Integrated Risk Information System	
NCEA	National Center for Environmental Assessment	
OERR	Office of Emergency and Remedial Response	

OHEA Office of Health and Environmental Assessment

ACRONYMS/ABBREVIATIONS (continued)

Acronym/	
Abbreviation	Definition
ORD	Office of Research and Development
OSWER	Office of Solid Waste and Emergency Response
$\mathbf{P}_{\mathrm{particle}}$	Particle density (g/cm³)
PAH	Polynuclear aromatic hydrocarbon
PCBs	Polychlorinated biphenyls
pK_a	Chemical specific ionization constant
PRG	Preliminary Remediation Goals
RAGS	Risk Assessment Guidance for Superfund (U.S. EPA, 1989)
RfD	Reference dose
RfD_{abs}	Absorbed reference dose (mg/kg-day)
RfD_o	Reference dose oral (mg/kg-day)
RME	Reasonable maximum exposure
SA	Skin surface area available for contact (cm²)
SC	Stratum corneum
SCS	Soil Conservation Service
SEE	Standard error of the estimator
SF	Slope factor
SF_{abs}	Absorbed slope factor (mg/kg-day) ⁻¹
SF_o	Oral slope factor (mg/kg-day) ⁻¹
SF_d	Dermal cancer slope factor (mg/kg-day) ⁻¹
${\sf SFS}_{\sf adj}$	Age-adjusted dermal exposure factor (mg-yrs/kg-event)
SVOCs	Semivolatile organic compounds
TCDD	Tetrachlorodibenzo-p-dioxin
J_{event}	Lag time per event (hr/event)
t*	Time to reach steady-state (hr)
$t_{\rm event}$	Event duration (hr/event)
THQ	Target Hazard Quotient (non-cancer)

TRL Target Risk Level (cancer)

ACRONYMS/ABBREVIATIONS (continued)

Acronym/	
Abbreviation	Definition
t_{sc}	Turnover time for the stratum corneum (days)
95% CL	95% confidence level
95% LCL	95% lower confidence level
95% UCL	95% upper confidence level